K093291

Premarket Notification 510(k) Summary

Submitter's Name:

Varian Medical Systems, Inc.
3100 Hansen Way, E-110
Palo Alto, CA 94304
Contact Name: Vy Tran
Phone: (650) 424-5731
Fax: (650) 424-5040
Date: October 2009

NOV 1 7 2009

Proprietary Name: Varian Interstitial Needles

Classification Name: System, Applicator, Radionuclide, Remote – Controlled
21 CFR 892.5700, Class II, JAQ

Common/Usual Name: Varian Interstitial Needles

Predicate Devices: Varian Interstitial Needles, K073133

Device Description:

The device is a family of closed-ended, interstitial needles and associated obturators to be used in conjunction with a high dose rate (HDR) brachytherapy afterloading device. The needles are available in either 17 gauge O.D. or 18 gauge O.D. and in lengths of 113mm, 200 mm, 250mm and 320mm. The associated obturators are inserted into needles to stiffen the needles during implantation of the needles into the patient and to stiffen the needles between radiation therapy fractions. The obturators are available in lengths of 113mm, 200 mm, 250mm and 320mm. The needles are provided unsterile with instructions for steam sterilization. The obturators are provided unsterile with instructions for steam sterilization.

Statement of Indications for Use: The Interstitial Needles are used with Varian High Dose Rate Afterloaders.

Technological Characteristics: Refer to the Substantial Equivalence Comparison Chart.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Vy Tran
Corporate Vice President, Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

NOV 17 2009

Re: K093291
Trade/Device Name: Interstitial Titanium Needles
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: October 16, 2009
Received: October 21, 2009

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093291

Device Name: Interstitial Titanium Needles

Indications for Use:

The Interstitial Needles are used with Varian High Dose Rate Afterloaders.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093291

(Posted November 13, 2003)